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OVERVIEW

Practicability of Developing a Performance Standard to Reduce Cigarette Ignition Propensity

U.S. Consumer Product Safety Commission

Jacqueline Jones-Smith, Chairman

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August 1993

Volume 1. Overview

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

The Chairman

August 9, 1993

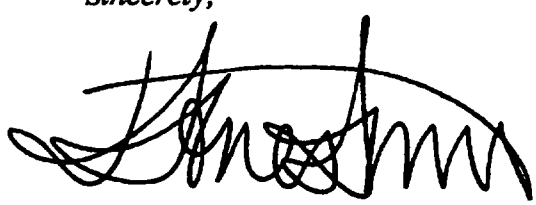
The Honorable Albert Gore
President of the Senate
Washington, D.C. 20510

Dear Mr. President:

In accordance with the provisions of the Fire Safe Cigarette Act of 1990 (Public Law 101-352), I am transmitting to the Congress the final report describing the research prescribed by the Act. The Commission and the National Institute of Standards and Technology have completed all of their assigned tasks. The findings are described in detail in the report transmitted with this letter.

While the Commission concludes that it is practicable to develop a performance standard to reduce cigarette ignition propensity, the effort to achieve such an objective is beyond both the jurisdiction and the technical capability of the agency. It would therefore be prudent for Congress, if it determines that pursuing this objective is in the national interest, to identify and delegate to a more appropriate agency the task of working with industry to develop a performance standard to reduce cigarette ignition propensity.

Sincerely,



Jacqueline Jones-Smith

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

The Chairman

August 9, 1993

The Honorable Thomas S. Foley
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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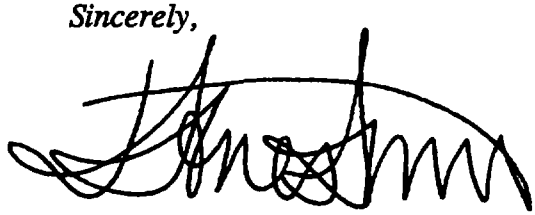

Jacqueline Jones-Smith

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Finally, the Commission offers special thanks to the members of the **Technical Advisory Group**, who spent many hours attending meetings and reviewing the work of NIST and the Commission. Every member added to our store of knowledge:

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I. Executive Summary

The Fire Safe Cigarette Act of 1990 directed the U.S. Consumer Product Safety Commission (Commission) and the National Institute of Standards and Technology (NIST) to carry out research designed to provide an assessment of the practicability of developing a performance standard to reduce cigarette ignition propensity, that is, the likelihood that a cigarette will act as an ignition source for mattresses, upholstered furniture, and similar items. This report describes the results of that research.

Practicability of Developing a Performance Standard

While the Commission concludes that it is practicable to **develop** a performance standard to reduce cigarette ignition propensity, it is unclear that such a standard will effectively address the number of cigarette-ignited fires. Further, the effort to achieve such an objective is beyond both the jurisdiction and the technical capability of the agency. It would, therefore, be prudent for Congress, if it determines that pursuing this objective is in the national interest, to identify and delegate to a more appropriate agency the task of working with industry to develop a performance standard to reduce cigarette ignition propensity.

To this end, broad parameters have been identified through the research specified in the Fire Safe Cigarette Act. The actual development of a standard would require the following:

(A) setting appropriate acceptance criteria for the ignition test method;

(B) establishing the appropriate series of tests for toxicity and setting acceptance criteria for each of those tests;

(C) estimating the safety benefits to be derived from the imposition of such tests; and

(D) determining the costs to cigarette manufacturers, consumers, and others of such a standard. The Commission emphasizes the importance of including toxicity tests in a standard, since even a small increase in toxicity could outweigh the beneficial effect of fewer fires.

The Fire Safe Cigarette Act directed the completion of several specific tasks, some of which were to be carried out by NIST, others by the Commission.

Research to be Completed by NIST:

Develop a Standard Test Method

This was the most important of the tasks specified by Congress: to develop a standard test method for measuring cigarette ignition propensity. NIST developed two test methods. One, the **mockup ignition test method**, measures the number of ignitions when cigarettes are placed on three types of simulated upholstery cushions with differing levels of ignition susceptibility. The second, the **cigarette extinction test method**, substitutes differing layers of filter paper for the furniture mock-ups and provides a more indirect measure of cigarette ignitability. Of these, the mock-up test is more suitable for use in a performance standard because it appears capable of providing better discrimination among cigarettes of high or moderate ignition propensity.

Test Commercial Cigarettes

NIST tested 20 selected brands of commercial cigarettes using the test methods described above. Several cigarettes performed significantly better than others on these tests, indicating that commercially marketed cigarettes differ in their probability of igniting soft furnishings, as measured by the mock-up test.

Conduct Laboratory Studies and Computer Modeling

NIST has developed a computer model of a multi-layer material (substrate) subjected to a stationary heat source with clear computer graphics and full technical documentation.

Research to be Completed by the Commission:

Implement a Fire Incident Study

The Commission conducted a study of the "characteristics of cigarettes, products ignited and smokers involved in fires." Through the services of contractors and local fire departments, it collected data on cigarette fires in eight U.S. cities and data from a companion survey of smokers in those same areas. Statistical analysis of the results indicated that, after adjusting for smoker characteristics and other cigarette specifications, the following cigarette characteristics significantly affected the risk of having a fire: filter presence and length, wrapping paper porosity, and whether the cigarette was packed in a soft pack or a box. Smoker characteristics that affected risk were gender, education, and (especially) family income.

These findings also suggest that cigarettes already in the marketplace differ in their likelihood of starting a fire.

Develop Information on the Societal Cost of Cigarette Fires

The Commission estimates that in 1990 the total direct cost of cigarette-ignited fire deaths, injuries, and property damage was approximately $4.0 billion (in 1992 dollars). The estimated cost of fatal and non-fatal injuries, which comprises a substantial portion of the total, includes estimates for medical and transport costs, productivity loss, pain and suffering, and legal and insurance costs. Fatal injuries, estimated at 1200 in 1990, account for about $2.5 billion of this total; hospitalized non-fatal injuries, chiefly thermal burns and smoke inhalation, account for more than $1.0 billion. Direct property damage from cigarette fires comes to about $500 million annually.

Develop Information on Toxicity and Health Effects (in consultation with the Secretary of Health and Human Services)

A panel of cigarette smoke toxicity experts developed a plan for testing low ignition-potential cigarettes. The purpose of the tests is to assure that whatever changes are made to achieve ignition resistance do not result in increased toxicity and adverse health effects beyond those that currently exist. Since the comprehensive set of proposed tests would cost about $330,000 per cigarette type, a reduced number of tests estimated at $6,900 per cigarette type was recommended as a practical first step implementation. Five cigarette types, including two prototype ignition-resistant cigarettes, two commercial brands, and a standard reference cigarette, were tested according to this reduced protocol. The results demonstrated that such an approach is practical and that the tests can distinguish differences among cigarette types.

Technical Advisory Group

The Act named a Technical Advisory Group (TAG) of 15 members representing the cigarette industry, government, the fire services, and health groups to advise the Commission and NIST on their work. The TAG met regularly during the course of this research, offering valuable comments at each stage. Several members of the TAG representing cigarette manufacturers gave or sponsored presentations of research that had been independently pursued, primarily related to the effect of air flow and fabric selection on the ignition propensity of cigarettes. The majority of the TAG supports the findings described above; a minority, almost always members representing cigarette manufacturers, disagrees, questioning primarily the validity of the test methods developed by NIST. They contend that the test methods have not sufficiently been shown to represent the way cigarettes ignite furnishings in real life. (The National Association of State Fire Marshals, although not represented on the TAG, agrees with this position.) Both majority and minority opinions are described in the TAG's final advisory report to the Commission, which appears at Appendix A.

Finally, the Commission notes that both laboratory and field studies indicate that some lower ignition propensity cigarettes already exist in the marketplace. Characteristics that have been associated with improved performance, in one or both of these studies, include lower paper porosity, smaller circumference, shorter filter, and lower tobacco density.

II. Introduction

The United States has the dubious distinction of being among the world leaders in fire death rates. On a per capita basis, about 50 percent more U.S. residents die in fires as in Europe or Japan. In 1990 the toll was almost 5,200 deaths, mostly in fires in residential structures; about 1,200 of these deaths occurred in fires started by cigarettes.

Cigarettes are not the leading cause of **fires** in this country, but they are by far the leading cause of **fire fatalities.** In spite of a significant decline during the last decade, cigarette fires accounted for 25 percent of all residential fire deaths during 1990, the most recent year for which data are available. In that year, cigarettes ignited an estimated 44,000 structural fires that caused about 1,200 deaths, 3,360 civilian injuries, and $400 million in direct property loss.

Nine years ago Congress enacted the Cigarette Safety Act of 1984 (Pub.L. 98-567, 98 Stat. 2925). That legislation created a Technical Study Group on Cigarette and Little Cigar Safety to study the technical and commercial feasibility, economic impact, and other consequences of developing cigarettes with a minimum likelihood to ignite upholstered furniture or mattresses. The Technical Study Group consisted of 15 members appointed to represent government, industry, fire service organizations, and medical and public health groups.

Several physical characteristics of cigarettes were proposed as possibly affecting ignition potential. These characteristics were systematically examined in laboratory work performed at the National Bureau of Standards, now NIST, using prototype cigarettes specially prepared by cigarette manufacturers. The tests identified tobacco density, cigarette circumference, paper porosity, the amount of citrate, and (in separate tests) the presence of a filter as affecting the risk of ignition. Economic impact analyses and estimates of changes in fire loss from an ignition-resistant cigarette were prepared, as well as a study of the feasibility of collecting field data about cigarette-ignited fires.

In October 1987, the Technical Study Group issued its final report. The major findings were that, " it is technically feasible and may be commercially feasible to develop cigarettes with a reduced propensity to ignite upholstered furniture and mattresses." However, the group also made specific recommendations for additional research in the area of cigarette fire safety.

The Fire Safe Cigarette Act of 1990 (Pub. L. 101-352; 104 Stat. 405) responds directly to those recommendations. It directed the Commission and the National Institute of Standards and Technology (NIST) to complete the research recommended by the Technical Study Group and to assess the practicability of developing a performance standard to reduce cigarette ignition propensity. (A copy of the Act is included at Appendix B.) The following tasks were assigned:

To be Completed by the National Institute of Standards and Technology:

- o *develop a standard test method to determine cigarette ignition* propensity,
- o compile performance data for cigarettes using this test method, and
- o conduct laboratory studies on and computer modeling of ignition physics to develop valid, user-friendly predictive capability.

To be Completed by the Commission:

- o design and implement a study to collect baseline and follow-up data about the characteristics of cigarettes, products, and smokers involved in fires,
- o develop information on societal costs of cigarette fires, and
- o develop information on changes in the toxicity of smoke and resultant health effects from cigarette prototypes (in consultation with the Secretary of Health and Human Services, and at a cost of not more than $50,000).

The Fire Safe Cigarette Act also established a Technical Advisory Group (TAG) to advise and assist the Commission and NIST in carrying out their work. The membership of the TAG consisted primarily of the same members who had served on the earlier Technical Study Group. The TAG met regularly throughout the course of the Act, actively participated in assessing the progress of the various tasks, and prepared a final advisory report that appears separately at Appendix A.

This is the third and final report required by the Fire Safe Cigarette Act. It describes the work undertaken to complete the tasks set forth above and assesses the practicability of developing a performance standard to reduce cigarette ignition propensity. Separate volumes provide additional details about the technical work on each task.

III. Summary of Research

A. Test Method Development

The Fire Safe Cigarette Act directed NIST to develop a standard test method to determine cigarette ignition propensity. The work was a follow-on to research described in the final report of the Technical Study Group in 1987.

In that report, NIST described several characteristics of cigarettes that were found to be related to their ignition propensity, based on tests conducted on a specially made series of experimental cigarettes. Those tests were performed using several different combinations of fabrics and upholstery filling materials (substrates) to represent and model the ignition performance of soft furnishings. The characteristics that affected the risk of ignition were tobacco density, cigarette circumference, paper porosity, presence of a filter, and, to a lesser extent, the addition of citrate to the wrapping paper.

Because the original experimental cigarettes were no longer available in sufficient quantity to complete the work, a new series of experimental cigarettes was provided by the cigarette manufacturers, intended to repeat the range of characteristics of the original. Five of the remade experimental cigarettes were selected to serve as calibration for the test method under development.

Mockup Ignition Method: The ignition of furniture or bedding by a cigarette is a highly interactive process; that is, properties of the substrate and of the cigarette play equally critical roles in determining whether or not ignition will occur. In order to develop a reliable test that could be used repeatedly over many years with the expectation that it will yield consistent results, particular care was needed to select the appropriate test materials.

A mockup consisting of a single layer of raw cotton duck fabric over polyurethane foam was selected. Cotton duck, which is commonly known as canvas, was chosen for several reasons. It is used in large quantities by the military and there are military specifications for its construction. These facts help to assure that it will be available indefinitely, and that its properties will remain consistent. Cotton duck also has ignition characteristics that allow discrimination among cigarettes *within the ignition propensity range of both the experimental cigarettes and current commercial cigarettes.* This point is crucial to the reliability and validity of the test method. Some fabrics will be ignited by all cigarettes; others will not be ignited by any cigarette. Such fabrics are of no use to discriminate among various cigarettes.

Cotton duck fabric is manufactured in several weights of varying susceptibility to ignition by a cigarette. The test procedure includes performing the test on three different weights of cotton duck (and in one case, an added layer of polyethylene film between the fabric and foam), with 48 replicates per test. The tests allow for the examination of cigarettes across a broad range of ignition propensity performance.

The ignition process is a subtle one, and it is readily affected by air movement. In actual fire situations, cigarettes may lie in various positions on and within furnishings, and air movement in the vicinity is thought to encompass a range from essentially zero upward. While actual air flows are not quantified, air flow velocities are likely to be variable, randomly oriented with respect to the cigarette, and low. For the test, NIST chose to use a slightly-modified version of the test chamber developed by the cigarette industry. This chamber is a closed plastic box that has a prominent "chimney" at the top to allow smoke to exit and an equal amount of air to flow back in. Conditions within the box are essentially still; what air movement exists is caused by the rising smoke and replacement air flow. NIST chose this condition because it is within the range of actual conditions, and it requires minimal effort to obtain a repeatable test environment.

Cigarette Extinction Test Method: NIST also investigated the feasibility of a test method that could discriminate over a wide range of cigarette ignition propensities with more easily standardized materials. The substrate materials finally selected were 3, 10, and 15 layers of standard cellulosic filter paper that effectively provide varying thermal absorption. Thus, as more layers are added, more of the heat of the cigarette is drawn away, and the more likely the cigarette is to self-extinguish. It should thus take more layers of paper to cause a more ignition-prone cigarette to self-extinguish in the test.

Interlaboratory Study: A major element of the development of both test methods was the "round robin" series of tests to demonstrate the reproducibility of the method. NIST arranged the participation of nine laboratories, including Federal and state government laboratories, cigarette industry laboratories, and a commercial testing laboratory. Each lab tested five prototype cigarettes, selected from remakes of the original set of experimental cigarettes, using both the mockup ignition method and the cigarette extinction method. The labs were provided with a written protocol for conducting the tests and all of the necessary test materials, including the experimental cigarettes.

The results of the interlaboratory tests indicate that the test methods are repeatable and reproducible within acceptable limits. While NIST believes either method is appropriate for routine use in measuring cigarette performance, the Mockup Ignition Test Method is more suitable for use in a performance standard

because it provides better discrimination among cigarettes at the higher range of ignition propensity.

The development of the two test methods constitutes the most important task under the Fire Safe Cigarette Act of 1990. Much of the discussion during the Technical Advisory Group meetings, and a significant amount of correspondence, concerned this work. Throughout the process of developing the tests, many decisions and selections had to be made. The information underlying these selections, and the bases for the decisions made, were the subject of considerable attention and controversy.

Members of the TAG representing cigarette manufacturers have introduced considerable data disputing the validity of the test conditions as representative of real life conditions, particularly with regard to fabric selection and air flow conditions. In one series of tests, a variety of upholstery fabrics purchased at retail was substituted for the cotton duck fabrics and purportedly tested according to the NIST protocol, using five experimental cigarettes of varying ignition propensity according to the 1987 NIST research. This research suggested that with some of the fabrics there was a reversal of ranking from the NIST tests; that is, cigarettes that performed well on the NIST tests had many ignitions, while cigarettes that performed badly had few ignitions. However, there was no evidence that **in the aggregate** the rankings were reversed.

One cigarette manufacturer also commissioned a study by the Battelle Memorial Institute of cigarette ignition tests conducted under a variety of air flow conditions. These data, introduced nearly at the end of the 3 year research period, also purported to indicate that the introduction of air flow into the test chamber, even at a rate of 0.1 ft./min., showed reversals of ranking from the results that would have been obtained from the NIST test. Although NIST is confident that its test method reasonably reflects what happens in the real world, it acknowledges that if data emerge to establish that changes are needed, the test methods could be modified.

Conclusions: NIST has developed two separate methods for measuring the propensity of cigarettes to ignite soft furnishings. The test methods are repeatable and reproducible within reasonable limits. Further, based on research conducted for the Technical Study Group during 1984 to 1987, they adequately reflect what happens in the real world when cigarettes are dropped on furnishings. The mock-up ignition method is more suitable for use in a performance standard.

A complete description of the test method development research is at Volume 2 of this report, "Test Methods for Quantifying the Propensity of Cigarettes to Ignite Soft Furnishings."

B. Testing of Commercial Cigarettes

In accordance with the directives of the Fire Safe Cigarette Act, NIST compiled performance data on a limited number of commercial cigarettes, using both test methods. The 20 cigarettes tested were selected from among more than 500 "packings" available on the commercial market at the time of testing. NIST selected 14 cigarettes that represent a significant proportion of the market in terms of sales figures, and 6 others that were expected to yield reduced ignition propensity because of their physical characteristics.

Because it was anticipated that many of the cigarette types would exhibit high ignition propensity, an abbreviated protocol was employed. This was based upon the assumption that if a cigarette displayed 100 percent ignitions on the most ignition-resistant substrate, the number of replicates could be reduced for the remaining substrates.

With one minor exception, all of the 14 best selling cigarettes ignited the test fabrics in all tests. Of the six cigarettes expected to display reduced propensity, almost all showed fewer ignitions on the hardest-to-ignite fabric, and at least one differentiated at the intermediate level. Similar results were obtained using the cigarette extinction method.

The testing of commercial cigarettes has provided a limited baseline of data for comparison purposes. In addition, it has demonstrated the high ignition propensity of commercial cigarettes in general compared to the experimental cigarettes. It has shown that some cigarettes on the market have a lower ignition propensity when tested in accordance with the test method developed by NIST. A detailed report of the test results is included in Appendix G of Volume 2.

C. Ignition Physics and Computer Modeling

The Fire Safe Cigarette Act directed NIST to conduct laboratory studies on and computer modeling of ignition physics to develop valid, user-friendly predictive capability. The plan intended at the outset has been modified somewhat by the complexity of the mathematical modeling and by the exigencies of the test method development project. However, NIST has developed computer models of a multi-layer cushion (substrate) subjected to a stationary heat source, a model of a burning cigarette lying on a substrate, and a protocol to use the two together. A description appears in Volume 3 of this report, "A Computer Model of the Smoldering Ignition of Furniture."

D. Cigarette Fire Incident Study

The Fire Safe Cigarette Act directed the Commission to collect data about the characteristics of cigarettes, smokers, and materials ignited in cigarette fires. Using two independent contractors, the Commission conducted a field study of cigarette fires and a survey of smokers in the communities where the fires occurred. The primary purpose of the study was to determine whether any physical characteristics of currently manufactured cigarettes were significantly associated with the risk of fire, after controlling for other cigarette and smoker characteristics.

Data Collection on Fire Incidents

The National Fire Protection Association was the contractor for the field study. With the cooperation of fire departments in Baltimore, MD; Cleveland, OH; Columbus, OH; Dallas, TX; Denver, CO; Houston TX; Philadelphia, PA; and Portland, OR, the contractor collected data over a 13 month period, from December 1991 through December 1992. During that time, 564 fires were reported for which the attending fire department could determine the identity of the smoker and the brand of cigarette believed to have started the fire.

Data Collection on Smokers

Mathematica Policy Research, Inc., the Commission's contractor for the comparison group of smokers, collected demographic and cigarette preference data from a sample of smokers in the same geographical areas served by the eight participating fire departments. The sample was drawn by random digit dialing from telephone exchanges within the fire department service areas. Information was collected on all smokers in a given household, as reported by one adult member of the household. After the elimination of data from households not located within the fire department service areas and from households where fires had occurred within the last year, 1,611 smokers comprised the sample that served as a comparison for the fire incident group.

Data obtained from Manufacturers

Research carried out during 1984-87 identified several physical characteristics of cigarettes that significantly affected their risk of igniting upholstery materials in laboratory tests. The characteristics included tobacco density, circumference, paper porosity, the amount of citrate additive, and the presence of a filter. Since many of these characteristics cannot be determined from physical inspection, the Commission solicited these specifications from manufacturers, who submitted the requested data about the cigarettes that they currently manufacture.

Results

The data were analyzed using a statistical procedure known as logistic regression. This is a rigorous method of analysis by which many different demographic and cigarette characteristics can be analyzed simultaneously to determine the strength of their respective associations with the risk of fire. Interactions between demographic and cigarette characteristics can also be examined.

The demographic variables included in the analysis were household income, education, gender, race, age, and city of residence. One demographic variable, the number of cigarettes smoked daily, was collected but discarded from the analysis because of coding discrepancies between the fire and smoker groups. Cigarette characteristics included in the analysis were tobacco column length, filter length, circumference, tobacco density, amount of tobacco, menthol, paper porosity, citrate additive (to the wrapping paper), and pack type (soft pack or box).

After controlling for all smoker characteristics, **several cigarette characteristics were found to have a significant effect on the risk of fire: (a) the presence and length of a filter, (b) wrapping paper porosity, and (c) pack type.** Specifically, a higher fire risk was observed for unfiltered cigarettes, for cigarettes with a short rather than a long filter, for cigarettes with higher paper porosity, and for cigarettes from a soft pack rather than a box. Significant interactions of household income with both education and race were found, and a significant interaction between pack type and gender. (The excess fire risk for soft pack cigarettes was only statistically significant among male smokers.)

The smoker characteristics that were found to be significant were: (a) income, (b) education, and (c) gender. Income had a more profound effect on risk than any other smoker or cigarette characteristic. Families with an income of less than $10,000 a year were six times as likely to have a fire as families with an annual income of $20,000 or more.

Various sensitivity tests were conducted to determine how dependent the logistic regression modeling was on certain aspects of the data. Areas of investigation included: the sensitivity of the regression modeling to the low fire reporting rate in Columbus, OH; to the use of self vs. proxy reporting (i.e., obtaining information directly from the smoker vs. from another household member); to the cluster sampling of the smoking households in the smoker survey; and to the effect of excluding cases where data on income or education were not available. The sensitivity tests indicated that the results described above were not significantly affected by any of these issues.

Discussion

Some of these epidemiological findings confirmed laboratory findings, some did not. Paper porosity was found to be significant in both laboratory and field studies. Tobacco density and cigarette circumference were significant in laboratory tests but not in the field study. It should be noted, however, that while the range of these characteristics in the field study included a few values at either end of the spectrum of characteristics examined in experimental cigarettes, most of the values for density and circumference among currently manufactured cigarettes were distributed closely around the mean. The fact that no significant differences were found may merely reflect the small sample size at either end of the range.

Results from a single epidemiological study cannot be determined to be definitive. By nature field studies are less rigorous than those conducted in a laboratory, where extraneous variables can be more rigidly controlled. The possibility cannot be ruled out that some of the characteristics shown to be significant may be surrogates for other cigarette characteristics unknown at this time. Only a few have been examined.

On the other hand, field studies have the advantage of relating directly to real life situations. The observed high risk for unfiltered cigarettes and cigarettes with a high paper porosity has been confirmed in laboratory studies. The effect of filter length, though not suggested previously, is a logical extension of that finding.

In summary, the results suggest that cigarettes currently on the market differ significantly in their risk of starting a fire, even after controlling for smoker characteristics.

A detailed analysis of the fire incident study and the smoker survey is at Volume 4 of this report.

comprehensive four-tiered sequential series of tests and a more practical first-step alternative. A limited number of cigarettes were tested using the first step alternative series.

The Commission finds that the panel of health experts established the framework for a reasonable evaluation of the toxicity of low ignition potential cigarettes. Candidate prototypes could be compared with the brand they would replace in the marketplace or with a standard reference cigarette. However, additional technical work is necessary to establish the most reasonable series of tests and to set appropriate acceptance criteria.

The importance of pairing a performance test for cigarette ignitability with a corresponding assurance of no increased adverse health effects requires emphasis. Toxicity testing is a necessary component of the development of a performance standard for a reduced ignition potential cigarette. This aspect of developing a performance standard will require more work than any other. Although cigarette manufacturers face no current restrictions on the manufacture of cigarettes sold to the public, if modifications to current cigarettes were required to make them less likely to start fires, there would be an equal obligation to ensure that no increased adverse health effects result.

4. Commercial Feasibility

Economic research pursued under the Cigarette Safety Act of 1984 established the technical feasibility of modifying cigarettes to increase ignition resistance. Some of the changes were estimated to be achievable with only small changes in the cost of producing cigarettes. The research did not examine the acceptability of such cigarettes to smokers.

The current Act required no additional work on commercial feasibility, and the legislative history makes it plain that none was intended. At meetings of the TAG, several manufacturers have described several smoker acceptability tests that they conducted using prototype ignition-resistant cigarettes. The results indicated a low degree of smoker acceptability.

However, both the fire incident study and the NIST tests of commercial cigarettes provide evidence that some cigarettes with a reduced ignition potential are **already in the marketplace**. A degree of consumer acceptability has therefore already been established.

5. Cost/Benefit

The Commission has made no estimates of the cost to the public of a performance standard to reduce cigarette ignitability. The maximum benefits,

however, can be derived from estimates of the current societal cost of cigarette fires as described above. It is unlikely that any performance standard will prevent all cigarette fires. The estimated level of effectiveness would depend on factors such as the stringency of the test (where the acceptance criteria are set) and its precision in accurately predicting ignitability on the range of materials found in U.S. homes.

Although the Commission concludes that the test method developed by NIST bears a reasonable relationship with real life conditions, it notes that additional tests of the kind carried out by industry would be necessary to make the cost/benefit findings that might be required to promulgate a standard.

Summary of Practicability

In summary, the Commission concludes that it is practicable to develop a standard to reduce cigarette ignition propensity. However, the Commission notes that, in order to more fully address issues raised by other interests, additional work is needed. The Commission also concludes that such an effort is beyond both the jurisdiction and the technical capability of the agency. Therefore, the Commission respectfully suggests that should it be determined that pursuing the development of this standard is in the national interest, the Congress should identify and delegate to a more appropriate agency the task of working with industry to develop the desired performance standard.

NIST | UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg Maryland 20899

July 8, 1993

The Honorable Jacqueline Jones-Smith
Chairman
Consumer Product Safety Commission
Washington, DC 20207

Dear Chairman Jones-Smith:

I am pleased to provide you with the Technical Advisory Group's (TAG) final appraisal of the tasks being carried out under the Fire-Safe Cigarette Act of 1990 (P.L. 101-352). After summarizing our activities, we present our views on the six tasks being performed by the Consumer Product Safety Commission (CPSC) and the National Institute of Standards and Technology (NIST) and our assessment of the practicability of developing a performance standard to reduce cigarette ignition propensity (IP). This letter is timed to provide input to your August 10, 1993 final report to the Congress, and most of our comments are based on interim versions of the task products. Nonetheless, we feel our assessment is valid and germane to your needs.

The chronology of our activity under the Act is as follows. Public Law 101-352 was enacted on August 10, 1990. The initial appropriation was received by CPSC on November 29, and the first funding was transferred to NIST on December 17. You appointed the TAG members by December 26. As under the Cigarette Safety Act of 1984, the membership represent:

- Federal agencies (5 members),
- cigarette manufacturing (4 members),
- public health organizations (2 members),
- fire safety organizations (2 members), and
- furniture manufacturing (2 members).

Eleven TAG meetings have been held on February 1, 1991, March 21, 1991, June 3, 1991, October 31, 1991, January 24, 1992, April 16, 1992, June 15, 1992, September 1, 1992, January 28-29, 1993, April 29-30, 1993, and June 11, 1993. A notice of each meeting was published in the Federal Register. The public audience at the meetings has been almost exclusively by technical and legal staff of the member organizations. We repeat our appreciation for the support of CPSC project staff in organizing the TAG meetings and distributing the materials needed to perform our functions.

The meetings have focused on reviews of project directions and results, both of work performed directly under the Act and also under the sponsorship of the tobacco industry. Discussion of technical and programmatic issues has been vigorous. The TAG membership is sharply divided in many facets of its assessment of the work performed under the Act. In general, where there are two

disparate views reflected in this report, the four cigarette industry representatives comprise the minority.

I. APPRAISAL OF TASKS UNDER "COMPLETION OF FIRE SAFETY RESEARCH"

With one month remaining in the lifetime of the Act, the TAG is confident that CPSC and NIST staff will complete all six of the mandated tasks. Eleven of the members of the TAG find that the work performed under the Fire Safe Cigarette Act of 1990 meets both the specific directives of the Act and responds to the overall intent. The four cigarette industry representatives, supported by industry-supported or -generated data and analyses, have expressed strong criticism of the quality and suitability of many of those products. Their assertions have generally been found non-persuasive by the other eleven members. Specific manifestations of both these positions appear under the discussion of the individual tasks.

A. NIST Tasks:

1. Develop a standard test method to determine cigarette ignition propensity. The TAG feels that this is the most important of the tasks and, as such, it has received the most attention. The TAG members have reviewed near-final documentation of the test method development.

Conducting new research and building on research performed under the direction of the Technical Study Group (TSG) under the Cigarette Safety Act of 1984 and related work performed by the cigarette industry, NIST has developed two test methods:

- The *Mock-up Ignition Test Method* uses three types of simulated upholstery cushions, each with a different cigarette ignition susceptibility. Each assembly (substrate) consists of a top layer of one of three weights of cotton duck fabric; a cushion of a polyurethane foam; and, in the least susceptible substrate, a thin layer of thermoplastic film in between. The performance measure is whether or not the mock-up is ignited by the cigarette placed on it.

- The *Cigarette Extinction Test Method* replaces the more complex substrate with 3, 10, or 15 layers of standard cellulosic filter paper. The performance measure is whether the cigarette extinguishes before burning its full length, i.e., whether the substrate absorbs enough heat from the cigarette coal to extinguish the cigarette.

Eleven members of the TAG have accepted the two methods and commend them as successful completion of this task, believing that both methods have valid links (comparable to many current fire test methods) to real-world fire scenarios of concern. NIST has incorporated most of the relevant physics and chemistry of such ignitions, while replicating the real-world hazard to sufficient, but differing extents. Both tests offer the use of a graded measure of performance, where a range of acceptable levels can be set by the regulator, although neither NIST nor the TAG have addressed specific regulatory criteria. Ignition propensity measurements using the two tests are consistent with each other and with other IP data. These TAG members also accept the provided basis for using only flat substrates, conducting all testing without externally-imposed air flow, and use of the selected substrate materials. The test materials are deemed likely to be available, with long-term consistency, in the foreseeable future. In general, the eleven are not persuaded by the cigarette industry representatives' assertions that the test methods are inaccurate or inappropriate.

The eleven members also find that the nine-laboratory study showed that the two methods are of useful reproducibility. The lab-to-lab variation in the proportion of ignitions is comparable to other fire test methods currently being used to regulate materials which may be involved in unwanted fires.

By contrast, the four cigarette industry members are sharply critical of the NIST research and the resulting methods. They assert the report contains conjecture on selections and assumptions made in developing the proposed test method. They further make the following assertions. Many of the explanations are contrary to research results at NIST and elsewhere. The proposed method employs substrates rarely, if ever, used in upholstered furniture or mattresses. One of the criteria used by NIST to select the cotton duck fabrics was that they would show large fractions of ignitions by popular commercial cigarettes; similar criteria were used in the design of the Extinction Method as well. The fabrics' chemical and physical properties are not representative of furniture or mattresses. They show inverse relationships between ignitions and fabric weight compared to commonly-used commercial fabrics. Extensive cigarette industry research data indicate an interaction between substrate and cigarette characteristics resulting in the conclusion that cigarette ignition propensity rankings are substrate dependent. The proposed tests were subjected to interlaboratory studies that made use of a limited, non-random selection of experimental cigarettes. Studies by NIST and other laboratories with the duck fabrics also indicate that the crevice configuration, which was excluded from the proposed NIST test method and is of concern in real-world fire settings, produces results that are inconsistent with commercial fabrics, e.g., the crevice configuration is a less severe test than the flat configuration with the duck fabrics. With little consideration of commercial substrate characteristics, or data that relates the test method substrate to real-world substrates, the proposed test method has no obvious real-world connectivity. Effects of real-world environmental air flow on cigarettes were not investigated, even though cigarette industry data indicate that it can reverse the apparent ignition propensities of cigarettes. Similar effects which have not been investigated by NIST may result from humidity changes. During the NIST studies, certain cigarette characteristics were found to correlate with reduced ignition propensity. Little correlation was found between these characteristics and those found in the CPSC field study of cigarette fires (Task 4), further indicating the lack of a real-world relationship between the proposed test method and fires. Finally, they assert that other issues not adequately addressed or resolved by NIST include unacceptable short- and long-term reproducibility of the test method.

2. Compile performance data for (commercial) cigarettes using the standard test method. NIST has completed the testing of 20 commercial cigarettes. Fourteen of these are the best selling packings, comprising nearly 40% of total sales. The test results show that these consistently ignite the most difficult-to-ignite substrate in the Mock-up Ignition Test and burn their full length in the Cigarette Extinction Test Method. The remaining six packings tested have one or more physical properties suggesting their being less ignition prone. All of these packings showed reduced ignition propensity in the Mock-Up Ignition Test Method. Four of these packings rarely ignited the most difficult-to-ignite substrate; the other two ignited it in 40-70% of the tests. Three of the four packings showed reduced IP on the middle substrate as well. While the Cigarette Extinction Test Method is less sensitive to changes in IP, three of the packings showed markedly fewer full-length burns. All these differentiations are outside the variability of the test methods. In the combined test results of commercial and experimental cigarettes using both methods, there is one inconsistency in the results of testing of one commercial cigarette on one substrate using the Mock-Up Ignition Method.

The TAG thus observes that there are multiple brands of commercial cigarettes currently being sold that are of reduced ignition propensity, as measured by the NIST test methods.

3. Conduct laboratory studies on and computer modeling of ignition physics to develop valid, "user-friendly" predictive capability. In September, 1992, NIST published a personal-computer-based model of a multi-layer substrate subjected to a stationary heat source with computer graphics and full technical documentation. The model, an upgrade of the version developed under the prior Act, shows promise in replicating limited experimental data on ignition by a stationary heat source. The intent is to use the model in conjunction with a model of a burning cigarette (to be completed in June, 1993) to simulate the cigarette ignition process. The TAG acknowledges the first report as completion of this part of the task. The TAG has not yet received the final report containing the cigarette burning model and the protocol for using the two models together.

Two of the cigarette companies have recently requested copies of the software. In a preliminary review, one has noted that the program executes in a relatively short time, has improved numerics compared to the original version, and is easier to use if all the input parameters are known. However, the model is limited in use because of the absence of the partner cigarette burning model and poor handling of oxygen diffusion. Use of the model would be promoted by having a catalogue of the thermal and kinetic properties required by the model for different fabrics and foams.

NIST has performed several examinations of aspects of the physics of the ignition process in developing both the test methods and the computer models. These have been tightly related to the development of the test methods and the computer models. They include: chemical kinetic profiles (via thermogravimetry) of fabric decomposition in air, analysis of cigarette-to-substrate heat transfer, analysis of oxygen transport to the ignition site, development of a small heat source to simulate the energy flux from the cigarette coal, generation of ignition delay time and ignition temperature data (as functions of the oxygen level, weight of substrate fabric, padding, and applied heat flux) for model verification, and measurement of ignition environment by infrared thermography.

B. CPSC TASKS:

4. Design and implement a study to collect baseline and follow-up data about the characteristics of cigarettes, products ignited, and smokers involved in fires. The aim of this study was to examine whether any physical characteristics of currently-manufactured cigarettes affected the risk of fire, after controlling for all other known smoker and cigarette characteristics. Working with the fire departments in eight cities, the National Fire Protection Association (NFPA), under contract to CPSC, has obtained data on 564 smokers (and their cigarettes) involved in fires. A second contractor, Mathematica, obtained telephone data about 1611 smokers who did not have fires. The TAG has reviewed a draft report from NFPA.

Using a logistic regression model, and after controlling for all other variables, four cigarette characteristics were found to have a statistically significant effect on the risk of a fire: the presence and length of a filter, paper porosity, and pack type (soft pack or box). The last was more pronounced among men than among women. Education level, gender, and especially income level were significant smoker characteristics.

The systematic, wide variation of certain composition factors (e.g., tobacco density, circumference, paper porosity, and citrate in the paper) of the experimental cigarettes in the TSG research enabled analysis of their impact on ignition propensity. Commercial cigarettes do not necessarily lend themselves to similar analysis. For instance, most of the commercial cigarettes in this study were in

a narrow range of tobacco density, which was a pronounced factor identified in the TSG research. In addition, the cigarette industry uses additives other than citrates to the paper. It is thus noteworthy that two factors were identified as affecting ignition propensity in both this and the TSG studies: presence of a filter and paper porosity.

Eleven members of the TAG find that this study shows that cigarettes currently on the market differ significantly in their risk of starting a fire, even after controlling for smoker characteristics. The eleven members realize that the particular characteristics shown to be significant may be surrogates for some other cigarette properties and smoker characteristics, unknown at this time. Despite only eight cities participating, the eleven members feel that it is unlikely that brand preferences peculiar to these localities may have influenced the results, or that a larger sample size would have yielded major differences in the principal conclusions.

By contrast, the four cigarette industry representatives note that this study did not find a statistically-significant association between reduced tobacco density (or reduced amount of tobacco), reduced cigarette circumference, or the presence of citrate in cigarette paper and the incidence of fires. These factors are three of the four cigarette design parameters that were reported in the TSG laboratory experiments to affect ignition propensity. The four assert that the presence of a filter was not reported in the 1984-87 research conducted by NIST to be a significant variable affecting ignition propensity and was not studied further by NIST under the current legislation. It is also noteworthy that demographic variations among smokers were found to be associated with fire incidence to a far greater extent than cigarette design characteristics. The field study findings raise serious questions concerning the real-world predictive value of the Mock-up Ignition Test and the Extinction Test. The cigarette design and packaging characteristics for which statistical significance was reported in the field study are based on analyses of main and first-order interaction terms. Limitations on sample size have been reported by CPSC to preclude examination of higher-order interactions for the variables that were reported to have statistical significance. The CPSC field study should be interpreted in light of this limitation.

5. Develop information on societal costs of cigarette-ignited fires. The TAG has received a rough draft and heard a presentation of estimates of the costs of smoking fire injuries by the National Public Services Research Institute, a contractor to CPSC. Based on 1990 estimates of (civilian and fire fighter) fatalities and injuries resulting from cigarette-initiated fires in structures, the annual cost to society is estimated to be $3.6 billion, with direct property damage estimated to cost an additional $0.4 billion. These estimates are based on a combination of new research, a comprehensive review of existing literature, and the latest cost estimation techniques. The TAG has received a next draft, but did not have sufficient time to evaluate it prior to transmitting this report.

Eleven members of the TAG find the presented work to be quite thorough. Significant benefits would accrue should cigarettes of reduced IP acquire an increased share of the market.

The four TAG cigarette industry members believe that the CPSC and its contractor used questionable assumptions and inappropriate data to arrive at a hugely inflated cost estimate. Moreover, other studies show substantial declines in careless smoking-related fires (58%) and fire deaths (45%) from 1980 through 1991.

6. Develop information on changes in the toxicity of smoke and resultant health effects from cigarette prototypes: This task reflects the concern that a small increase, due to new cigarette types, in the serious health risk that, in the view of eleven members of the TAG, already causes over 400,000 smoking-related deaths annually could overbalance the benefits that would be achieved from the reduction of fires. Since the Act limits spending to $50,000, the TAG agreed with CPSC staff that any significant amount of actual testing of prototypes was precluded and that the preparation of a recommended testing protocol would be of high value. CPSC staff, in consultation with the Department of Health and Human Services (DHHS) and with nominations from the TAG, composed a panel of five eminent scientists in the field of cigarette smoke toxicity, supported by CPSC and DHHS representatives, to assist in developing such a plan.

Based on scientific information developed by the expert panel, the CPSC/DHHS recommended and the TAG concurred that a four-tier, performance-based test protocol be utilized for assessing possible changes in toxicity of new, low IP cigarettes. A performance-based test was judged scientifically appropriate due to the significant number of possible design variations of low IP cigarette prototypes. The protocol comprises: (1) analysis of specific chemical constituents in cigarette smoke incorporating the FTC protocol, (2) *in vitro* testing, (3) examination of changes in human smoking behavior of low IP cigarettes that might change smoke dose and exposure, and (4) *in vivo* (animal) testing. Each of the tiers (except number 3) contains specific tests that use currently-accepted and currently-used scientific technology that may be employed to demonstrate the health and/or safety for products in the U.S. marketplace and for Federal regulation of consumable products. However, not all health effects of serious concern are addressed at this time because of the impracticability or non-existence of adequate tests, high costs, or long periods needed for testing. Definition of acceptable levels of performance was deemed to be beyond the scope of the Act. Estimated costs for conducting all but the third tier (for which no estimates are available) are about $330,000 per prototype.

Conducting a selected subset of tests represents a practical first step in implementing the plan. With input from the experts and the TAG, CPSC/DHHS recommended the measurement of tar, nicotine, carbon monoxide, pH, benzo(a)pyrene, and tobacco-specific nitrosamines from tier I, and a salmonella mutagenicity assay from Tier II. The estimated direct cost for this first step is $6,900. CPSC directed testing of five cigarette types to demonstrate the practicability of this first step testing. The data indicate that cigarette types can be distinguished by these toxicological parameters and that the cost estimates in the plan are reasonable.

Eleven members of the TAG recognize the Toxicity Testing Plan as a substantial contribution to evaluating the changes in toxicity associated with low ignition-potential cigarettes and finds that it is a reasonable approach, especially considering the constraints imposed on the expert panel (funding, time, complexity).

The four cigarette industry representatives agree that changes in smoke chemistry may be expected to result from large modifications in cigarette design and that careful study of potential health effects that may be associated with such changes is appropriate. They note, however, that the plan has limitations as a guidance document and that issues of experimental design and the interpretation of results will require more detailed assessment than was permitted under the constraints imposed by the Act. Definition of acceptable performance for modified cigarettes also is critical. The proposed toxicity plan raises serious questions, but provides few answers at this stage of development.

II. ASSESSMENT OF THE PRACTICABILITY OF DEVELOPING A PERFORMANCE STANDARD TO REDUCE CIGARETTE IGNITION PROPENSITY

The TAG has spent considerable time discussing how to provide you with technical advice on this topic. We realize that, under the Consumer Product Safety Act (P.L. 92-573), tobacco and tobacco products are specifically not included as consumer products. However, under the Fire Safe Cigarette Act of 1990 (P.L. 101-352), the Congress requires such an assessment. The TAG presumes that there are some technical elements likely to be common to any regulatory process and that these are similar to those used by the CPSC. CPSC staff have provided us with such a list, and these elements are addressed below.

A. TEST METHOD TO CHARACTERIZE PRODUCT PERFORMANCE

Eleven members of the TAG recommend the use of the Mock-up Ignition Test Method for use in a product performance standard for the reasons given under Task 1, above. While routine measurement of the relative ignition propensity of cigarettes is feasible using either of the two methods, this method is preferred over the Cigarette Extinction Method because it demonstrated better distinction among both the commercial and experimental cigarettes. The NIST report contains all the necessary materials for initiating the adoption of either method as a voluntary consensus standard by either ASTM or the National Fire Protection Association (NFPA).

These members also find that use of the test method is likely to potentiate reduced fire losses. The current best-selling cigarettes produce consistent ignitions of all substrates in the two test methods. New cigarette designs intended to produce fewer fires and fire deaths will need to demonstrate a significant reduction in test ignitions, compared to the current best-sellers. There are no data indicating the converse, namely that cigarettes that produce fewer ignitions in the test methods will produce greater fire losses.

As noted in the above discussion of the test methods (see Task 1), the four cigarette industry TAG members believe that these are not predictive of real-world cigarette ignition propensity. They have found in their studies that ignitions of commercial fabrics under likely real-world environmental conditions may be increased by adoption of a performance standard based on the proposed NIST test methods. In addition, the predicted short-term reproducibility of the proposed test methods (40%) makes them unsuitable for use in product development or in establishing a performance standard. Longer term reproducibility has not been examined and may even be more limited in view of the reported characteristics of the cotton duck fabric relied on by NIST. Thus, at this state of development, neither of the proposed test methods should be adopted as a basis for measuring the ignition propensity of cigarettes. They assert the methods are not predictive of real-world fire risk and could be counterproductive.

B. ACCEPTANCE CRITERION

The TAG believes that the setting of acceptability criteria is in the domain of the regulator. The NIST report does provide some assistance, however. The interlaboratory evaluation of the method showed that individual test labs could differ by about 40 percent, defining the limit of resolution for use in any future regulations. There are also data to "calibrate" the method at the high and low ends

of the ignition propensity scale: the commercial cigarette test data (Task 2) establish an indication of performance for the cigarettes associated with current fire losses; some experimental cigarettes never or rarely ignited a variety of substrates.

The four cigarette industry representatives believe that consideration of acceptance criteria presupposes that a reproducible and predictive test method has been developed. At this state, they contend that neither condition has been met.

C. HEALTH EFFECTS

Eleven members of the TAG support use of the CPSC toxicity testing plan in the development of a performance-based requirement for low ignition-potential cigarettes entering the market. The plan is a reasonable approach to collect data needed to evaluate major health risks. It could be adopted as guidance or incorporated into mandatory or voluntary consensus standards. The TAG also recognizes that improvements in toxicity testing and risk evaluation may occur and should be considered during possible future revisions of the plan.

These eleven members of the TAG believe that the primary responsibility for the safety of cigarette products belongs to the cigarette manufacturers. No agency currently has regulatory authority over cigarettes. They believe that new products should not increase the risk of adverse health effects to the public above the existing risks resulting from currently-marketed cigarettes, unless such increased risk is outweighed by the reduced number of deaths and injuries from the fires prevented. The toxicity of a candidate low IP cigarette should be compared to a) the specific marketed brand/type intended for replacement or comparable marketed brands/types for a non-replacement candidate, and/or b) standard reference cigarettes. Toxicity criteria remain to be set.

The four representatives of the cigarette industry, as noted under Task 6, contend that the plan is insufficient for guiding regulation. They do agree that careful study of potential health effects is appropriate.

D. ECONOMIC AND COMMERCIAL FEASIBILITY OF LOW IGNITION PROPENSITY CIGARETTES

Eleven members of the TAG have considered the extensive series of studies conducted and sponsored by the cigarette industry subsequent to the TSG's final report in October, 1987. They conclude that these studies are not persuasive in changing the TSG's findings that "it is technically feasible ... to develop cigarettes that will have a significantly reduced propensity to ignite upholstered furniture or mattresses."

Indeed, the eleven members of the TAG find that cigarettes of reduced ignition propensity are already being marketed, presumably at a profit. This is based on the results of the CPSC field study (Task 4) and the NIST commercial cigarette tests (Task 2). Thus, these members conclude that some manufacturers have found it commercially feasible to produce and sell cigarettes of reduced ignition propensity. In addition, the TAG notes that these reduced IP current commercial cigarettes also show yields of tar, nicotine and carbon monoxide that are no different in the aggregate from the best-selling cigarettes. Thus, the eleven conclude that it is possible to achieve reduced ignition propensity

in a commercially feasible cigarette without increasing smoke toxicity (assuming that toxicity is represented by these three yields).

The four TAG members representing the cigarette industry dispute this, citing shortcomings of the methods used, as noted in the above sections on the two Tasks. They also note that assessment of the economic and commercial feasibility of low IP cigarettes was not included in the Act. Further, the six commercial brand styles tested under Task 2 have a minimal market share, indicating unacceptability to the overwhelming majority of smokers. Consumer testing (by the industry) of prototype cigarettes incorporating the low-IP features identified in the TSG study has found that they are not acceptable to smokers.

E. BENEFIT/COST ANALYSIS OF LOW IGNITION PROPENSITY CIGARETTES

Eleven members of the TAG find that a net benefit to the nation can be derived from the introduction of low ignition propensity cigarettes into commerce, assuming the incremental adverse health effects do not outweigh the fire safety benefits. This is based on three observations. First, in appraising the NIST model of economic impact in its Final Report, the TSG concluded that the cost of modified cigarettes need not be large:

> "The overall effects of the cigarette modifications considered may result in only small changes in the price of cigarettes, unemployment, health care costs, life expectancy, and the financial status of the affected industries and professions."

Second, as noted under "Economic and Commercial Feasibility," cigarettes of reduced ignition propensity are already being marketed in the same price range of the most popular brands.

Third, there are likely to be significant benefits from low IP cigarettes. The TSG correlation of mock-up results with chair tests and the current NIST test method report indicate that positive test results can be expected to be indicative of reduced ignitions for significant portions of the real-world furnishings population, at least for coarse changes in test performance.

The four TAG members representing the cigarette industry disagree. They assert that cost/benefit analysis was not authorized or addressed in the current legislation and cannot begin to be conducted until a reproducible and predictive standard test method has been developed and proposed performance standards or acceptance criteria have been advanced. A wide range of critical economic considerations also were identified in the 1984-87 TSG studies as critical inputs to any assessment of the costs versus benefits of reduced ignition propensity cigarettes. It was found that a cost/benefit conclusion could not be reached on the data then available, and there has been no further study of these issues. Cigarette industry data also indicate that a performance standard based on the NIST methods may increase the propensity of cigarettes to ignite commonly-used cigarette fabrics in real-world conditions and thereby produce detriments rather than benefits. The four assert that cost/benefit analysis also should include consideration of alternate approaches to improved fire safety. They contend that California upholstered furniture flammability standards have proven feasible and effective in reducing fires and fire deaths beyond any known or realistic prediction of the impact of modification in cigarette design.

III. CONCLUSION

In conclusion, the Technical Advisory Group, by a vote of 11 to 4, believes that sufficient technology and information is available to deem practical the development of a performance standard to reduce cigarette ignition propensity.

Sincerely,

Richard G. Gann, Ph.D.
Chairman, Technical Advisory Group
Fire-Safe Cigarette Act of 1990
and
Chief, Fire Science Division
Building and Fire Research Laboratory

cc: Members, Technical Advisory Group

Public Law 101-352
101st Congress

An Act

To direct the completion of the research recommended by the Technical Study Group on Cigarette and Little Cigar Fire Safety and to provide for an assessment of the practicality of a cigarette fire safety performance standard.

Aug. 10, 1990
[H.R. 293]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Fire Safe Cigarette Act of 1990.

SECTION 1. SHORT TITLE; FINDINGS.

15 USC 2054 note.

(a) SHORT TITLE.—This Act may be cited as the "Fire Safe Cigarette Act of 1990".

(b) FINDINGS.—The Congress finds that—

(1) cigarette-ignited fires are the leading cause of fire deaths in the United States,

(2) in 1987, there were 1,492 deaths from cigarette-ignited fires, 3,809 serious injuries, and $395,000,000 in property damage caused by such fires,

(3) the final report of the Technical Study Group on Cigarette and Little Cigar Fire Safety under the Cigarette Safety Act of 1984 determined that (A) it is technically feasible and may be commercially feasible to develop a cigarette that will have a significantly reduced propensity to ignite furniture and mattresses, and (B) the overall impact on other aspects of the United States society and economy may be minimal,

(4) the final report of the Technical Study Group on Cigarette and Little Cigar Fire Safety under the Cigarette Safety Act of 1984 further determined that the value of a cigarette with less of a likelihood to ignite furniture and mattresses which would prevent property damage and personal injury and loss of life is economically incalculable,

(5) it is appropriate for the Congress to require by law the completion of the research described in the final report of the Technical Study Group on Cigarette and Little Cigar Fire Safety and an assessment of the practicability of developing a performance standard to reduce cigarette ignition propensity, and

(6) it is appropriate for the Consumer Product Safety Commission to utilize its expertise to complete the recommendations for further work and report to Congress in a timely fashion.

SEC. 2. COMPLETION OF FIRE SAFETY RESEARCH.

15 USC 2054 note.

(a) CENTER FOR FIRE RESEARCH.—At the request of the Consumer Product Safety Commission, the National Institute for Standards and Technology's Center for Fire Research shall—

(1) develop a standard test method to determine cigarette ignition propensity,

(2) compile performance data for cigarettes using the standard test method developed under paragraph (1), and

(3) conduct laboratory studies on and computer modeling of ignition physics to develop valid, user-friendly predictive capability.

The Commission shall make such request not later than the expiration of 30 days after the date of the enactment of this Act.

(b) COMMISSION.—The Consumer Product Safety Commission shall—

(1) design and implement a study to collect baseline and followup data about the characteristics of cigarettes, products ignited, and smokers involved in fires, and

(2) develop information on societal costs of cigarette-ignited fires.

(c) HEALTH AND HUMAN SERVICES.—The Consumer Product Safety Commission, in consultation with the Secretary of Health and Human Services, shall develop information on changes in the toxicity of smoke and resultant health effects from cigarette prototypes. The Commission shall not obligate more than $50,000 to develop such information.

15 USC 2054 note.

SEC. 3. ADVISORY GROUP.

(a) ESTABLISHMENT.—There is established the Technical Advisory Group to advise and work with the Consumer Product Safety Commission and National Institute for Standards and Technology's Center for Fire Research on the implementation of this Act. The Technical Advisory Group may hold hearings to develop information to carry out its functions. The Technical Advisory Group shall terminate 1 month after the submission of the final report of the Chairman of the Consumer Product Safety Commission under section 4.

Termination date.

(b) MEMBERS.—The Technical Advisory Group shall consist of the same individuals appointed to the Technical Study Group on Cigarette and Little Cigar Fire Safety under section 3(a) of the Cigarette Safety Act of 1984. If such an individual is unavailable to serve on the Technical Advisory Group, the entity which such individual represented on such Technical Study Group shall submit to the Chairman of the Consumer Product Safety Commission the name of another individual to be appointed by the Chairman to represent such group on the Technical Advisory Group.

15 USC 2054 note.

SEC. 4. REPORTS.

The Chairman of the Consumer Product Safety Commission, in consultation with the Technical Advisory Group, shall submit to Congress three reports on the activities undertaken under section 2 as follows: The first such report shall be made not later than 13 months after the date of the enactment of this Act, the second such report shall be made not later than 25 months after such date, and the final such report shall be made not later than 36 months after such date.

15 USC 2054 note.

SEC. 5. CONFIDENTIALITY.

(a) IN GENERAL.—Any information provided to the National Institute for Standards and Technology's Center for Fire Research, to the Consumer Product Safety Commission, or to the Technical Advisory Group under section 2 which is designated as trade secret or confidential information shall be treated as trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, and section 1905 of title 18, United States Code, and shall not be revealed, except as provided under subsection (b). No member or employee of the Center for Fire Research, the Consumer Product Safety Commission, or the Technical Advisory Group and

no person assigned to or consulting with the Center for Fire Research, the Consumer Product Safety Commission, or the Technical Advisory Group, shall disclose any such information to any person who is not a member or employee of, assigned to, or consulting with, the Center for Fire Research, Consumer Product Safety Commission, or the Technical Advisory Group unless the person submitting such information specifically and in writing authorizes such disclosure.

(b) CONSTRUCTION.—Subsection (a) does not authorize the withholding of any information from any duly authorized subcommittee or committee of the Congress, except that if a subcommittee or committee of the Congress requests the Consumer Product Safety Commission, the National Institute for Standards and Technology's Center for Fire Research, or the Technical Advisory Group to provide such information, the Commission, the Center for Fire Research, or Technical Advisory Group shall notify the person who provided the information of such a request in writing.

Approved August 10, 1990.

LEGISLATIVE HISTORY: H.R. 293:

CONGRESSIONAL RECORD, Vol. 136 (1990):
July 30, considered and passed House and Senate.

E. Toxicity Testing Plan

The Fire-Safe Cigarette Act directed the Commission, in consultation with the Secretary of the Department of Health and Human Services (DHHS), to develop information on changes in the toxicity of smoke and resultant health effects of cigarettes with a reduced probability of starting fires.

The reasons for considering the health implications of ignition-resistant cigarettes are compelling. There are about 50 million smokers in the U.S., of whom an estimated 434,000 die annually from adverse health effects associated with smoking. According to the Department of Health and Human Services, the societal cost of smoking in the U.S. is estimated at $68 billion per year in direct and indirect costs. Thus, even a small increase in the risk of an adverse health effect due to new cigarette types could result in a great increase in human and economic costs. If this occurs, it could counter the benefits achieved from the reduction of fires by new cigarette types.

The Act imposed a limit of $50,000 for evaluating health effects. Both the Commission and the TAG agreed that the spending limit precluded any significant amount of actual testing of cigarette prototypes, especially since the nature and extent of required testing had not been established. In consultation with Donald Shopland, MD, of the DHHS, and with the concurrence of the TAG, the Commission decided to convene a panel of health experts who would develop a toxicological testing plan. The experts would define the significant issues and recommend the tests necessary for a comprehensive assessment of health effects of low-ignition potential cigarette smoke.

The experts were selected from a list proposed by the TAG, the DHHS, and the Commission. Each prepared specific chapters of the final report:

JEFFREY E. HARRIS, MD, PHD, PROVIDED AN OVERVIEW OF THE ISSUES RELATED TO DEVELOPMENT OF A PLAN AND THE MAJOR HEALTH EFFECTS OF TOBACCO SMOKE.

HAROLD C. PILLSBURY, JR., DESCRIBED THE SMOKING MACHINE AND PROTOCOL FOR THE COLLECTION OF GASES AND PARTICULATE MATTER FROM CIGARETTE SMOKE.

DAVID M. BURNS, MD, DISCUSSED THE EFFECT OF SMOKING TOPOGRAPHY (INHALATION PROFILE) AND BIOLOGICAL INDICATORS OF TOBACCO SMOKE IN HUMANS.

DIETRICH HOFFMANN, PHD, PROPOSED TESTS FOR THE ANALYSIS OF TOXIC SMOKE CONSTITUENTS AND IN VIVO BIOASSAYS FOR CARCINOGENICITY.

GARY GAIROLA, PHD, SUGGESTED SHORT-TERM TESTS FOR THE EVALUATION OF TOXICITY.

Panel Findings

Adverse health effects that determine the nature of required toxicity tests include the following: lung and throat cancer, chronic obstructive lung disease, heart and vessel disease, male and female reproductive effects, fetal growth retardation, and psychophysiological addiction. Not all of these health effects can be addressed at this time because of the impracticality or non-existence of adequate tests, high costs, or long periods of time needed for testing.

Other major issues surrounding the testing included evaluation of sidestream smoke, analytical vs. *in vitro* vs. *in vivo* testing, machine reflection of human smoking behavior, performance vs. design-based testing, screening models, and disclosure of new additives or increased levels of existing additives.

A smoking machine protocol for measuring nicotine, carbon monoxide, and particulate matter (tar) was developed by the Federal Trade Commission. It is the only required toxicity testing for cigarettes in the U.S., and it prescribes no limits of acceptability. However, cigarette smoke contains more than 3,500 chemicals. The panel agreed that present knowledge on the adverse health effects and toxic constituents of cigarette smoke dictated further testing beyond the FTC requirements.

Since low ignition-potential cigarettes might cause changes in smoking behaviors and therefore modify the toxicity, altered human behavior may become a significant factor in exposure. Analysis of selected chemicals known to be associated with adverse health effects may not be sufficient to predict the net toxicity of the smoke. *In vitro* and *in vivo* testing are needed.

Health Effects Assessment Plan

After consideration of the testing proposed by the expert panel, and in consultation with DHHS, the Commission developed the following performance-based plan. Four sequential tiers of testing are proposed:

Tier I: chemical analyses of smoke: acidity and reduction/oxidation potential, carbon monoxide, hydrogen cyanide, and nitrogen oxides, aldehydes, volatile hydrocarbons, volatile nitrosamines, particulate matter (tar), catechols, nicotine, phenols, polynuclear aromatic hydrocarbons, and tobacco-specific nitrosamines.

Tier II: *in vitro* tests: *Salmonella* mutagenicity (Ames' assay) and mouse embryo fibroblast cell transformation assay.

Tier III: indicators of human smoking behavior: levels of cotinine and carbon monoxide in human subjects, smoker topography (puff volume, frequency, and draw velocity).

Tier IV: *in vivo* tests: mouse inflammatory lung response, hamster respiratory tract carcinogenicity, and mouse skin painting carcinogenicity.

Satisfactory performance at one tier would be required before proceeding to the next. The toxicities of the prototypes should be compared with marketed types intended for replacement or comparable marketed types, and standard reference cigarettes. However, the definition of acceptable levels of performance at any tier is beyond the scope of this plan. Moreover, it is beyond the direction given by the Act.

The FTC method is the basis for the mechanical generation of smoke constituents for the tests described in Tier I. However, the test protocol, especially in terms of puff volume, frequency, and draw velocity, may need to be revised based on actual smoking behavior as measured in Tier III. Unless consistent correlation of testing results of mainstream and sidestream smokes can be shown, both must be separately collected and tested.

Additives in the prototypes exceeding the current levels of use or new additives must be disclosed to determine whether additional testing is needed. Improvements in toxicity testing and risk evaluation may occur in the future and should be considered during possible revisions of the plan.

First implementation step

Completion of all four testing tiers is costly relative to the present level of testing required by FTC ($330,000 in direct costs for Tiers I, II, and IV). Therefore, a stepwise implementation of the plan is suggested.

A practical subset of recommended tests should comprise, as a minimum, limited testing from Tiers I and II. (Subsequent steps should consider the more comprehensive recommended test plan.) The estimated direct cost of this first step was $6,900 per cigarette type tested, although the Commission was able to contract for the work for somewhat less. The tests included: from Tier I, tests for nicotine, tar (FTC), carbon monoxide, whole smoke pH, benzo(a)pyrene, and tobacco-specific nitrosamines; from Tier II, the Salmonella mutagenicity ("Ames") assay. Smoke and condensate were generated by machine according to the FTC protocol.

The Commission contracted with two laboratories to conduct this limited test protocol on five cigarettes-- two commercial brands, two low ignition-potential prototypes, and a standard reference cigarette. The results indicate that the plan will provide data that can distinguish differences in toxicities among cigarette types. The demonstration also shows that the cost estimates are reasonable and the implementation of limited tests from Tiers I and II is feasible.

A complete review of the toxicity findings is at Volume 5, Toxicity Testing Plan.

F. Societal Cost of Cigarette Fires

Introduction

The Fire Safe Cigarette Act directed the Commission to "develop information on the societal costs of cigarette-ignited fires." Volume 6 of this report presents a summary of the latest available data on the estimated economic costs of deaths, injuries and property damage resulting from structural fires started with smoking materials. These are the costs most likely to be significantly affected by action to reduce the ignition propensity of commercial cigarettes. The estimates do not include other costs to the public associated with fires and fire safety but less directly related to cigarette-ignited fires.

A substantial amount of new information regarding the cost of injuries was accumulated for this task. Greatly improved estimates of costs associated with fatal and non-fatal burn, anoxia and other injuries were developed, including estimated medical costs, transport costs, productivity losses, pain and suffering, and legal and health insurance administrative costs. The estimates, presented in summary below, are reasonably applicable to injuries resulting from cigarette-ignited fires. Estimates for the numbers of fatalities and non-fatal injuries and for property damage are from CPSC's Directorate for Epidemiology, the U.S. Fire Administration, and the National Fire Protection Association.

Estimated Societal Costs

During 1990 the total cost of cigarette-ignited fire deaths, injuries and property damage was estimated at approximately $4.0 billion (in 1992 dollars, excluding costs associated with public expenditures on fire protection, firefighting services, and other costs less directly associated with or affected by cigarette-ignited fires). This comprises over 1,200 deaths and nearly 7,000 treated civilian and firefighter injuries in residential and non-residential smoking fires (99 percent of total estimated injury costs -- and virtually all deaths -- involve civilian casualties) as well as nearly $0.5 billion in property damage. Fatal injuries account for about $2.5 billion (60 percent) of this total; hospitalized, non-fatal injuries -- chiefly thermal burns and anoxia -- account for over $1.0 billion. Estimated total annual costs for all injuries are shown in Table 1; detailed cost components on a per-case average basis are estimated in Table 2.

Table 1
Societal Costs of Cigarette-Ignited Fire-related Injuries
($ million, 1992 dollars)

Cost Component	Estimated Cost	Percent
Medical	76	2.1
Transport	1	<0.1
Productivity Loss	705	19.7
Pain & Suffering	2,763	77.1
Legal	35	1.0
Insurance/Admin	5	0.1
TOTAL	$ 3,585	100.0

Source: Miller, et al, National Public Services Research Institute

Detailed breakdowns of injury cost components on a per-case average basis are estimated for burns and anoxia (the major injury categories) in Table 2.

Table 2
Estimated Average Per-case Cost Components
for Cigarette-Ignited Burn and Anoxia Injuries
(1992 dollars)

	Burns			Anoxia		
	Hospitalized			Hospitalized		
	Fatal	Non-Fatal	ER Only	Fatal	Non-Fatal	ER Only
Medical	11,199	50,963	698	10,860	4,434	617
Transport	453	211	26	416	253	111
Productivity	530,000	34,000	2,750	530,000	11,000	2,750
Pain & Suff.	1,470,000	785,000	10,700	1,470,000	105,000	9,500
Legal	19,000	8,500	0	19,000	1,500	0
Ins./Admin.	816	3,582	51	789	328	51
TOTAL	2,000,000	875,000	14,000	2,000,000	125,000	13,000

Source: NPSRI. Estimates are based on breakdowns for civilian injuries

Medical costs were derived from an exhaustive review of data from a variety of medical data bases, with detailed corroboration and cross-checking. Estimates for productivity losses, litigation costs, and emergency transport are drawn from existing and newly-generated data. Pain and suffering estimates, which comprise a substantial proportion of total costs, are largely based on a thorough analysis of jury verdicts in fire injury cases. Each of the cost components is based on averages of observed ranges and represents a conservative approach to estimating costs.

Conference on Fire-related Injuries

A national conference of leading burn care experts was held to discuss trends in treatments, costs and outcomes of fire-related injuries. The conferees noted the substantial reduction in the mortality rates for hospitalized burn patients over the past two decades led to an increase in the proportion of resources devoted to extremely severe burn cases. This emphasis on badly burned victims may tend to increase total costs, especially since treatments being developed for the most severe burn and anoxia cases are likely to be very expensive. Thus, costs can be expected to continue to be very high for fire-related injuries. On the other hand, functional and cosmetic outcomes for less severe burns have improved dramatically in recent years, and increasing outpatient management of burn injuries in lieu of hospitalization may tend to curb potential cost increases.

Potential Benefits of Lower Ignition Propensity Cigarettes

The Act does not call for an analysis of the benefits - or costs - of any specific set of performance or other requirements for cigarette fire safety. The 1987 TSG final report contained analyses of potential benefits and costs associated with a variety of possible cigarette modifications, but no specific test method or performance requirements were presented or analyzed. The range of potential benefits would depend on the nature, technical and commercial feasibility, and projected effectiveness of any possible requirements. The available data suggest, however, that substantial fire safety benefits could accompany reductions in the ignition propensity of commercial cigarettes. While some currently-marketed commercial cigarettes may have lower ignition propensity, uncertainty about the commercial feasibility of lower ignition propensity cigarettes remains. Similarly, the potential net benefits (i.e., net of economic costs) are unknown, and may be especially sensitive to any possible health effects of altering the chemical composition of cigarette smoke.

Although the societal cost estimates may be conservative, not all smoking fires are addressable by widespread use of lower ignition propensity cigarettes. Therefore, the cost estimates may overstate the likely level of benefits of mandatory or other action to reduce cigarette ignition propensity. Any future analysis of the economic efficiency of lower ignition propensity cigarettes would, however, involve estimating the likely benefits (and costs) to the public of a reasoned set of alternatives aimed at improved cigarette fire safety.

IV. Technical Advisory Group

The Fire Safe Cigarette Act established a Technical Advisory Group (TAG) to advise and work with the Consumer Product Safety Commission and NIST on the implementation of the Act. The members were, in general, the same individuals who served on the Technical Study Group (TSG) for the Cigarette Safety Act of 1984.

The Technical Advisory Group met regularly and discussed every aspect of the work in progress. Both NIST and Commission staff made regular presentations about the progress of the work. In addition, several members of the TAG representing cigarette manufacturers or their designated representatives presented the results of research independently undertaken. Most of the industry presentations were intended to raise doubts about the validity of the NIST test method. In addition to the questions about air flow and fabric selection, which have been discussed earlier in this report, the presentations were intended to contradict some of the statistical conclusions from the earlier report of the Technical Study Group in 1987.

The TAG issued a final advisory opinion about the research pursued under the Act and an assessment of the practicability of developing a performance standard. The majority of the TAG supported the research findings. A minority, almost always members representing the cigarette manufacturers, disagreed, questioning primarily the adequacy of the test method developed by NIST. In support of their opinion, the manufacturers introduced a large volume of oral and written testimony. The TAG's final advisory opinion includes a summary of both majority and minority positions; they appear at Appendix A of this report.

V. Practicability of Developing a Performance Standard

The research described above is relevant to the final and most critical of the directives of the Fire Safe Cigarette Act - an assessment of the practicability of developing a performance standard to address cigarette ignition propensity. There are at least five aspects to such an assessment:

1. development of an acceptable test method
2. appropriate acceptance criteria for such a test
3. possible adverse health effects
4. economic feasibility
5. cost/benefit determinations

A discussion of each of these aspects follows.

1. Development of an acceptable test method

The first requirement for a performance standard is the development of a valid and reliable test method for measuring cigarette ignition performance. (A valid test is one that measures what it is intended to measure, in this case the likelihood that a cigarette will start a fire under real life conditions. A reliable test is one that produces similar results when repeated by operators at the same or other laboratories, assuming reasonable diligence in following the test protocol.) NIST's test method research was the single most important task specified in the Act.

The Commission shares NIST's and the TAG's conclusion that the research during the present study, together with research undertaken from 1984 to 1987, establishes the validity and reliability of their test methods within reasonable limits.

Members of the TAG who represent cigarette manufacturers, as well as representatives of the National Association of State Fire Marshals, claim that the test methods developed by NIST are inadequate. Their primary contention is that the test method developed by NIST is not sufficiently related to real life conditions, particularly in terms of the test fabrics and air flow conditions in the test chamber. They have introduced considerable testimony to this effect at TAG meetings and have submitted a large quantity of written materials.

Representatives of cigarette manufacturers have introduced data indicating that under some air flow conditions and with some fabrics, there is a reversal of ignition propensity ranking from the NIST tests; that is, cigarettes that showed few ignitions using the fabrics and air flow conditions specified in the NIST test method showed many ignitions when tested on certain other fabrics or under certain other

air flow conditions, while the reverse was true for cigarettes with a demonstrated high ignition potential in the NIST test. In other words, a reversal of the expected rankings was observed.

Some of the data presented by industry (e.g., a report about air flow prepared by the Battelle Memorial Institute and data from testing fabrics commonly used in upholstered furniture) was introduced at too late a date to be thoroughly considered for this report. While NIST is confident that its test method reasonably reflects what happens in the real world, it acknowledges that if data emerge to establish that changes are needed, the test methods could be modified.

The Commission also notes that it is not necessary for the test method to discriminate adequately among low and high ignition propensity cigarettes on all fabrics and under all air flow conditions. It is only necessary that it do so in the aggregate. Few test methods or remedial strategies are effective under all possible circumstances.

The accurate and reproducible representation of a real-life process involving fire in a controlled laboratory environment is never easy because of the large number of variables involved. It is not possible in one test, or even a limited series of tests, to reproduce all real life conditions under which a cigarette may start a fire. Insofar as possible, a test must narrow the range of variables to allow examination of the performance characteristic of interest.

It is not unusual for standardized tests to employ materials and test conditions that do not exist or rarely exist in real life. The need to simulate real life must be balanced against the need to use standardized materials that will provide reliable results. If the materials and conditions chosen for a test adequately serve as surrogates for the variety of substrates and conditions found in real life, then their use is acceptable. In this case, prior research under the TSG established the ignition performance of experimental cigarettes using several different fabric and cushion combinations. Experimental cigarettes with those same characteristics were used in developing the present test method.

Cigarette manufacturers have implicitly approved the use of surrogates in their research. Repeatedly they have used fabrics treated with different levels of smolder promoters such as sodium or potassium ions as a surrogate for fabrics with varying levels of ignitability. The fabric selected by NIST, an as-received, undyed cotton duck, was chosen because of the stability of its specifications and performance over time. The three weights used represent varying levels of ignitability and provide flexibility in setting acceptance criteria.

The choice of air flow conditions presents a similar problem. It is not practical to represent all air flow conditions, and strict control of managed air flow can be difficult. The actual location and position of fire-causing cigarettes is not fully known, but epidemiological evidence suggests that the most typical furniture location is within a crevice formed by cushions. Air flow rates and air availability under such conditions are probably random, variable, and typically low. The negligible air flow rate used in the NIST tests seems fair and reasonable, and has not been persuasively refuted by industry research.

2. Acceptance Criteria

In order to translate a test method into a performance standard, one must set an appropriate acceptance (pass/fail) criterion or criteria. How many ignitions, if any, are acceptable for a prescribed number of tests? The ideal level of acceptability is one that achieves the maximum benefits in safety at the least cost, and allows for the known variability in flammability test results.

The Fire Safe Cigarette Act did not direct the Commission or NIST to establish an appropriate acceptance criterion. However, the Commission has no reason to believe that an appropriate acceptance level could not be established for the present test. Some additional lab work might be required to establish the optimal cut-off point for the number of ignitions allowed.

NIST's tests were conducted on three different weights of cotton duck, representing differing levels of ignitability, with 48 replicates per fabric. The results for the cigarettes tested suggest that acceptable differentiation might be achieved using only two of these cotton duck fabrics, and possibly fewer replicates. Test results for specific cigarettes on specific fabrics tended to be dichotomous - no or few ignitions as opposed to all or nearly all ignitions, a finding that might facilitate setting an appropriate acceptance criterion.

3. Health Effects

In addition to being a major cause of fire deaths, cigarettes are the single, major cause of premature mortality in the United States, directly responsible for an estimated 400,000 to 500,000 deaths annually. It is therefore essential to ensure that changes in the physical properties of cigarettes for the purpose of achieving reduced ignition potential do not result in additional adverse health effects. Even a small increase in human toxicity could outweigh the beneficial effects of fewer fires.

The $50,000 spending limit to develop information on the toxicity of ignition-resistant cigarettes precluded any significant amount of testing. Instead, a panel of health experts drew up a plan for such an assessment, including both a